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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,218	10/19/2005	Stevan Nielsen	17601.25a.1	8376
57360	7590	09/27/2010	EXAMINER	
WORKMAN NYDEGGER 1000 EAGLE GATE TOWER, 60 EAST SOUTH TEMPLE SALT LAKE CITY, UT 84111			OU, JING RUI	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,218	Applicant(s) NIELSEN ET AL.	
	Examiner JING RUI OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-40 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-40 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/29/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment filed on 06/29/2010. Claims 24-40 and 47-49 are pending. Claims 24 and 47 are independent. Claims 47-49 are newly added.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 24-40 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitations “an expandable member disposed through the housing” in claim 24, and “an expandable member disposed through the lumen of the housing and including a stop” in claim 47 do not have sufficient support in the original disclosure and are considered as new matter. Applicant should be noted that the expandable member 24 is located outside the housing and is not disposed through the housing.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 24-40 and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 24 and 47, it is unclear how the expandable member is disposed through the housing since the expandable is disclosed to be located outside the housing in the specification.

In claim 47, it is unclear how the expandable member has a stop since the stop is on the shaft as disclosed in the specification.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 24-26, 28-32, 34, 35, 38-40, and 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al (US Pat. No.: 7,291,129).

In regard to claims 24-26, 28-32, 34, 35, 38-40, and 47-49, Li et al discloses an apparatus comprising: a housing (11, 12, and 15); an expandable member (16 or 70); and a plurality of needles (21) coupled to the housing; wherein the expandable member is disposed from the distal end of a shaft coupled to the housing (Fig. 1 or 7A); an actuator (28) coupled to the plurality of needles; and a manifold (the cylindrical member

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with an injection portion 27 that connects the needle, Fig. 1); wherein the plurality of needles are coated with the closure agent (when the bulking agent is injected, some of the bulking agent must be coated on the needle); wherein each one of the plurality of needles comprises a distal tip, a distal aperture, and a lumen that couples the distal aperture to a source of closure agent (Fig. 2B); wherein the expandable member has a deployed configuration (Fig. 4).

8. Claims 24-32, 34, 35, 38-40, and 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow et al (US Pat. No.: 6,692,466).

In regard to claims 24-32, 34, 35, 38-40, and 47-49, Li et al discloses an apparatus comprising: a housing (12); an expandable member (20); and a plurality of needles (46) coupled to the housing; wherein the expandable member is disposed from the distal end of a shaft coupled to the housing (Fig. 1A); a stop (combination of 82 and 84); an actuator (57) coupled to the plurality of needles; and a manifold (59); wherein the plurality of needles are coated with the closure agent (when the therapeutic agent is injected, some of the bulking agent must be coated on the needle); wherein each one of the plurality of needles comprises a distal tip, a distal aperture, and a lumen that couples the distal aperture to a source of closure agent (Fig. 4A); wherein the expandable member has a deployed configuration (Fig. 4).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (US Pat. No.: 7,291,129) as applied to claims 24 above, and further in view of Epstein et al (US Pat. No.: 6,835,193).

In regard to claim 27, Li et al discloses all the limitations of the claim but fails to disclose a stop to limit translation of the plurality of needles into the tissue. However, Epstein et al teaches an apparatus comprising a stop (15 and 14) to limit translation of a needle into body tissue. At the time of the invention, it would have been obvious to

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modify the apparatus of Li et al to include a stop as taught by Epstein et al for allowing the control of the depth injection of the needle into the body tissue (Epstein et al, see Abstract).

11. Claims 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (US Pat. No.: 7,291,129) as applied to claims 24 above, and further in view of Janzen et al (US Pat. No.: 7,008,439).

In regard to claim 33, Li et al discloses all the limitations of the claim but fails to disclose at least one balloon coupled to the plurality of needles; wherein the balloon being the closure agent. However, Janzen et al teaches at least one balloon coupled to the needle; wherein the balloon being the closure agent. At the time of the invention, it would have been obvious to modify the apparatus of Li et al to include at least one balloon coupled to the plurality of needles and wherein the balloon being the closure agent as taught by Janzen et al. The suggestion/motivation for doing so would have been to easily fill up the balloon with the closure agent, to protect the closure agent from fast degradation by the body, and to maintain the closure agent within a specific location of the body for a longer period of time.

12. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (US Pat. No.: 7,291,129) as applied to claims 24 and 33 above, and further in view of Slater (US Pub. No.: 2002/0143291).

In regard to Claims 36 and 37, Li et al discloses all the limitations of the claims but fails to disclose a radiopaque marker disposed adjacent to the distal tip of each one of the plurality of needles and on the distal end of the shaft. However, Slater teaches a

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radiopaque marker (58) disposed adjacent to the distal tip of a surgical insertion tool (26). At the time of the invention, it would have been obvious to modify the apparatus of Li et al to include a radiopaque marker disposed adjacent to the distal tip of a surgical insertion tool as taught by Slater. Applicants should note that it was well-known to include a radiopaque marker/band adjacent to the distal tip of a surgical insertion tool to allow a surgeon to monitor the location of the insertion tool in the body.

13. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al (US Pat. No.: 6,692,466) as applied to claims 24 and 33 above, and further in view of Slater (US Pub. No.: 2002/0143291).

In regard to Claims 36 and 37, Chow et al discloses all the limitations of the claims but fails to disclose a radiopaque marker disposed adjacent to the distal tip of each one of the plurality of needles and on the distal end of the shaft. However, Slater teaches a radiopaque marker (58) disposed adjacent to the distal tip of a surgical insertion tool (26). At the time of the invention, it would have been obvious to modify the apparatus of Chow et al to include a radiopaque marker disposed adjacent to the distal tip of a surgical insertion tool as taught by Slater. Applicants should note that it was well-known to include a radiopaque marker/band adjacent to the distal tip of a surgical insertion tool to allow a surgeon to monitor the location of the insertion tool in the body.

Response to Arguments

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14. Applicant's arguments with respect to claims 24-40 and 47-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING RUI OU whose telephone number is (571)270-5036. The examiner can normally be reached on 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, UYEN (JACKIE) HO can be reached on 571-272-4696. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. O./
Examiner, Art Unit 3773
09/09/2010

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773